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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,099	09/22/2003	Stephen R. Gorfine	010692-004532US	1846

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,099	GORFINE, STEPHEN R.	
	Examiner	Art Unit	
	Christopher R. Tate	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003 and 12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *37-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed September 22, 2003 has been received and entered. Claims 37-65 are presented for examination on the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 37-65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 5,504,117 and over claims 1-62 of U.S. Patent No. 5,693,676. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed method and the claimed methods of US '117 and US '676 are each drawn to a method of treating an anal disorder including an anal fissure, anal ulcer, hemorrhoidal disease, and/or levator spasm and ameliorating pain associated therewith via administering a composition comprising an effective amount of a nitric oxide donor (such as nitroglycerin or L-arginine) to the anal area/anal canal of a subject in need thereof; as well as further including within the composition a corticosteroid and/or a local anesthetic. Further, the instant claims encompass or are encompassed by the claimed methods of US '117 and US '676.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 37-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loder et al. (Gut, 1993: Abstract P22/64 - ref AS in IDS of parent Appl. Nos. 10/021,168 and 08/970,447), Loder et al. (Dis Colon Rectum Mtg Abstracts,1993: Abstract T96/S25 - ref AT in IDS of parent Appl. Nos. 10/021,168 and 08/970,447) and Guillemot et al. (Dis. Colon Rectum, 1993 - ref AA in IDS of parent Appl. Nos. 10/021,168 and 08/970,447), in view of Jensen (1986: ref AU in IDS of parent Appl. Nos. 10/021,168 and 08/970,447) and Gallina (USP 4,514,384).

A method of treating an anal disorder including an anal fissure, anal ulcer, hemorrhoidal disease, and/or levator spasm and ameliorating pain associated therewith via administering a composition comprising an effective amount of a nitric oxide donor (such as nitroglycerin or L-arginine) to, or proximate to, the external anus and/or the affected area in the anal canal such as the distal anal canal of a subject in need thereof is claimed. Dependent claims including further including a corticosteroid and/or a local anesthetic within the composition.

The references by Loder et al. each teach topical ointment compositions comprising 0.2% of the nitric oxide donor glyceryl trinitrate (nitroglycerin) as the active ingredient therein for externally application to the anus so as to relax the anal sphincter due to pathogenic conditions such as anal fissures and hemorrhoids.

Guillemot et al. teaches in their pilot study a topical pharmaceutical composition containing a 5 mg dosage of nitroglycerin (applied internally to the anal canal via a balloon applicator) which may be useful *in situ* for treating anal pathologies such as anal fissures, and further discloses that it might be of value to try different doses of nitroglycerin to treat anal fissures as the use of 5 mg "might be an excessive dose concerning the anal sphincter" (see, e.g., abstract and pages 374-375, Results and Discussion).

The Loder and Guillemot et al. references do not teach the further inclusion of hydrocortisone or other analgesics to their pharmaceutical compositions.

Jensen and Gallina et al. teach pharmaceutical compositions comprising hydrocortisone and/or other topical analgesics to beneficially provide art-recognized pain-relief due to anal fissures and/or hemorrhoids (see, e.g., Jensen - abstract; Gallina - abstract, col 1, lines 18-26, and col 2, lines 9-68).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to topically administer a result-effective amount of a nitric oxide donor such as nitroglycerin to the affected external and internal anal area/anal canal of a subject suffering from an anal disorder such as anal fissures, hemorrhoids, etc, based upon the beneficial teachings provided by the primary references as a whole. It would also have been obvious to one of ordinary skill in the art to further include a conventionally employed analgesic and/or hydrocortisone within such a topical preparation based upon the beneficial teachings provided by the secondary references, as discussed above, and for the following reason. It is well known to be *prima facie* obvious to combine two or more ingredients (e.g., nitroglycerin and hydrocortisone and/or the

other topical analgesics) each of which is taught by the prior art to be useful for the same purpose (such as the method instantly claimed - i.e., to treat anal fissures, hemorrhoids, and related anal disorders) in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). The result-effective adjustment in conventional working conditions (e.g., determining an appropriate dosage amount or topical pharmaceutical form thereof such as using a suppository, gel, lotion, or an ointment which incorporates white vs. yellow parraffin as a well known equivalent carrier therein and/or topically applying such a composition to one or more affected anal areas - e.g., internal and external areas) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Please also note that the use of suppositories (as well as other conventionally employed topical pharmaceutical forms) to apply such pharmaceutical compositions to the anus/anal canal is notoriously well known and accepted in the art. Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1654